DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-628/S-001

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attention: Sarah J. Cantrell
Manager, Regulatory Affairs
6201 South Freeway, R7-18
Fort Worth, TX 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug application dated June 22, 2000, received June 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tobraflex (tobramycin and fluorometholone acetate ophthalmic suspension, USP). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated December 5, 2000, and January 25, 2001.

This supplement provides for revised draft labeling of the package insert, cartons, and containers to reflect the use of a new trademark, Tobraflex. Please note that the previous trademark, Tobrasone, will no longer be used in labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revision listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

There is a typographical error in the How Supplied section of the package insert. The corrected sentence should read "Tamper evidence is provided with a shrink band around the closure and neck area of the package."

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the draft labeling of the package insert and the immediate container and carton labels submitted January 25, 2001. This revision is a term of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-628/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Raphael Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research